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webinar series

William Atkinson, MD, MPH
Updates from the
February 2017 ACIP Meeting
March 16, 2017

Advisory Committee on Immunization Practices (ACIP)

- **The recommendations to be discussed are primarily those of the ACIP**
 - **composed of 15 experts in clinical medicine and public health who are not government employees**
 - **provides guidance on the use of vaccines and other biologic products to the Department of Health and Human Resources, CDC, and the U.S. Public Health Service**

ACIP Recommendations

- Recommendations approved by the Committee are just the first step
- Recommendations do not become official policy until
 - approved by the CDC Director, *and*
 - published in Morbidity and Mortality Weekly Report (MMWR)

Figure 1. Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2017.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded in gray.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs
Hepatitis B ¹ (HepB)	1 st dose	2 nd dose															
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2												
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose												
<i>Haemophilus influenzae</i> type b ⁴ (Hib)			1 st dose	2 nd dose	See footnote 4												
Pneumococcal conjugate ⁵ (PCV13)			1 st dose	2 nd dose	3 rd dose												
Inactivated poliovirus ⁶ (IPV: <18 yrs)			1 st dose	2 nd dose													
Influenza ⁷ (IIV)																	
Measles, mumps, rubella ⁸ (MMR)																	
Varicella ⁹ (VAR)																	
Hepatitis A ¹⁰ (HepA)																	
Meningococcal ¹¹ (Hib-MenCY ≥6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)																	
Tetanus, diphtheria, & acellular pertussis ¹² (Tdap: ≥7 yrs)																	
Human papillomavirus ¹³ (HPV)																	
Meningococcal B ¹¹																	
Pneumococcal polysaccharide ⁵ (PPSV23)																	

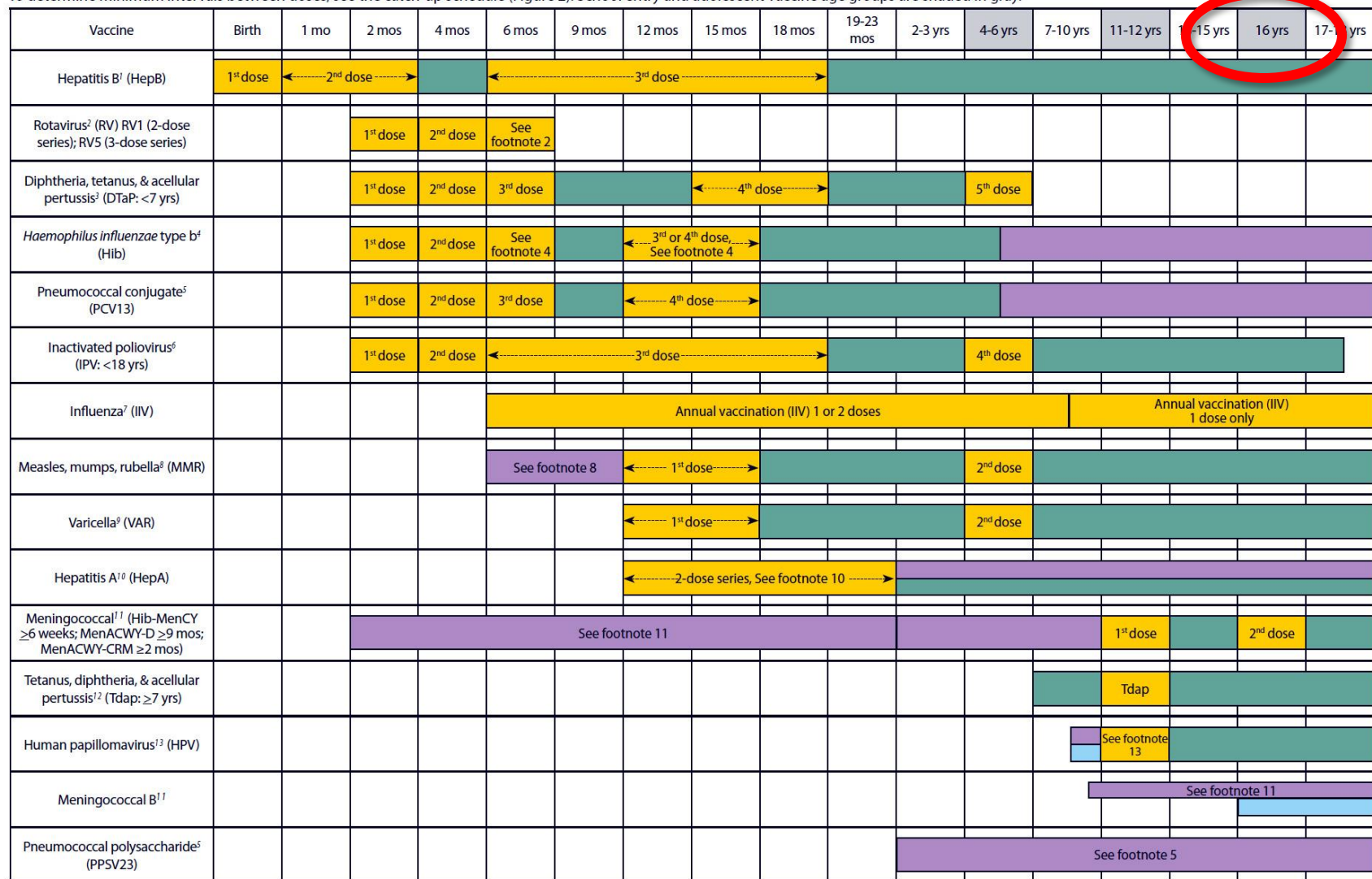
Range of recommended ages for all children
Range of recommended ages for catch-up immunization
Range of recommended ages for certain high-risk groups
Range of recommended ages for non-high-risk groups that may receive vaccine, subject to individual clinical decision making
No recommendation

NOTE: The above recommendations must be read along with the footnotes of this schedule.

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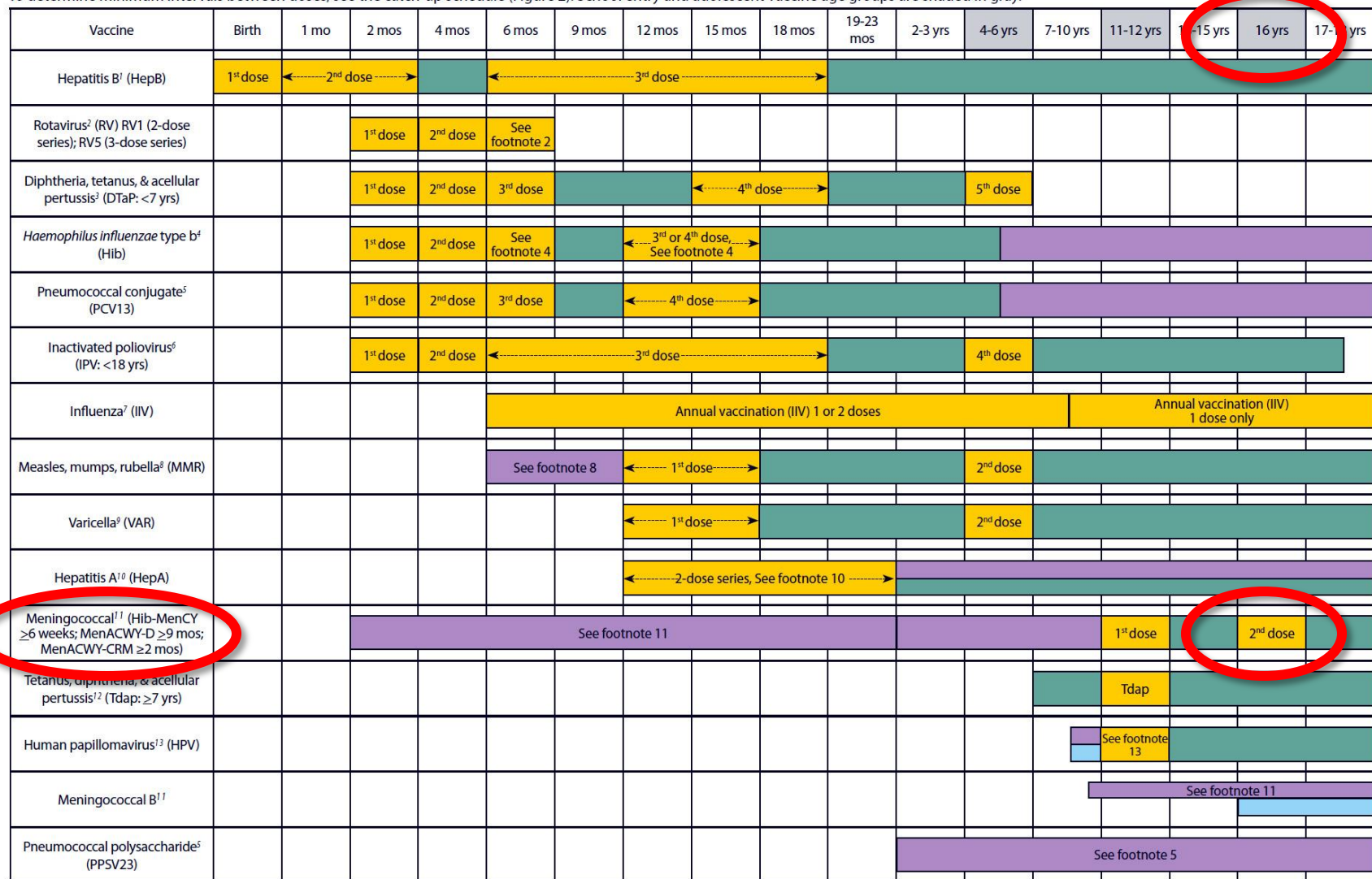
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2017 Child and Adolescent Schedule

Other Changes

- Live attenuated influenza vaccine removed from the figure and footnote
- Hepatitis B footnote – birth dose should be administered within 24 hours of birth (previously “before hospital discharge”)
- MenACWY recommended for HIV infected children and adolescents
- 2-dose HPV schedule
- 2 dose MenB (Trumenba) schedule

Figure 3. Vaccines that might be indicated for children and adolescents aged 18 years or younger based on medical indications

VACCINE ▼	INDICATION ►	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count (cells/ μ L)		Kidney failure, end-stage renal disease, on hemodialysis	Heart disease, chronic lung disease	CSF leaks/cochlear implants	Asplenia and persistent complement component deficiencies	Chronic liver disease	Diabetes
				<15% of total CD4 cell count	\geq 15% of total CD4 cell count						
Hepatitis B ¹											
Rotavirus ²			SCID*								
Diphtheria, tetanus, & acellular pertussis ³ (DTaP)											
<i>Haemophilus influenzae</i> type b ⁴											
Pneumococcal conjugate ⁵											
Inactivated poliovirus ⁶											
Influenza ⁷											
Measles, mumps, rubella ⁸											
Varicella ⁹											
Hepatitis A ¹⁰											
Meningococcal ACWY ¹¹											
Tetanus, diphtheria, & acellular pertussis ¹² (Tdap)											
Human papillomavirus ¹³											
Meningococcal B ¹¹											
Pneumococcal polysaccharide ⁵											

 Vaccination according to the routine schedule recommended	 Recommended for persons with an additional risk factor for which the vaccine would be indicated	 Vaccination is recommended, and additional doses may be necessary based on medical condition. See footnotes.	 No recommendation	 Contraindicated	 Precaution for vaccination
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*Severe Combined Immunodeficiency

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Figure 1. Recommended immunization schedule for adults aged 19 years or older by age group, United States, 2017

Vaccine	19–21 years	22–26 years	27–59 years	60–64 years	≥ 65 years
Influenza ¹	1 dose annually				
Td/Tdap ²	Substitute Tdap for Td once, then Td booster every 10 yrs				
MMR ³	1 or 2 doses depending on indication				
VAR ⁴	2 doses				
HZV ⁵				1 dose	
HPV–Female ⁶	3 doses				
HPV–Male ⁶	3 doses				
PCV13 ⁷					1 dose
PPSV23 ⁷	1 or 2 doses depending on indication				1 dose
HepA ⁸	2 or 3 doses depending on vaccine				
HepB ⁹	3 doses				
MenACWY or MPSV4 ¹⁰	1 or more doses depending on indication				
MenB ¹⁰	2 or 3 doses depending on vaccine				
Hib ¹¹	1 or 3 doses depending on indication				



Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection



Recommended for adults with additional medical conditions or other indications



No recommendation

2017 Adult Schedule Changes

- Live attenuated influenza vaccine removed
- 2-dose HPV schedule (if vaccination begins before age 15 years)
- Hepatitis B indications for people with chronic liver disease
- MenACWY recommended for HIV infected children and adolescents
- 2 dose MenB (Trumenba) schedule



February 22-23, 2017 ACIP Agenda

- **One Vote:**
 - **Hepatitis B vaccine in infants born to hepatitis B-infected mothers, updated recommendations and Vaccines for Children (VFC) vote**

February 22-23, 2017 ACIP Agenda

DISCUSSION ONLY TOPICS:

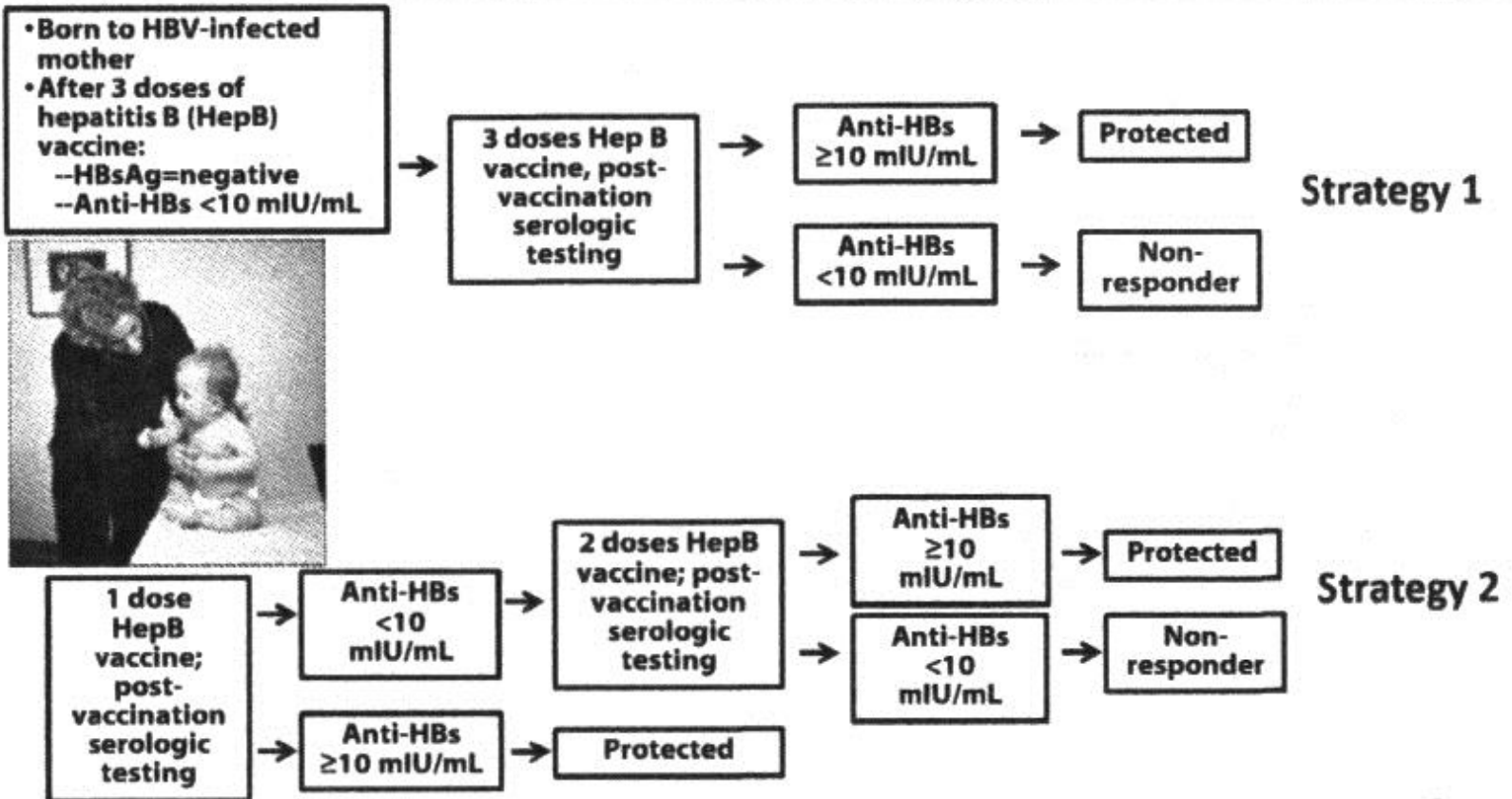
- Influenza
- Adult immunization
- Herpes zoster vaccines
- Meningococcal vaccines
- Global immunization update
 - Polio eradication
 - Dengue, Zika, Yellow Fever
- Vaccination errors
- Mumps disease and vaccine

Discussion of Hepatitis B Revaccination

- **Applies to infants born to HBsAg positive women**
- **Most infants respond to the initial HBIG and hepatitis B vaccine series**
- **Discussion focused on management of infants who do NOT respond to the initial postexposure prophylaxis**

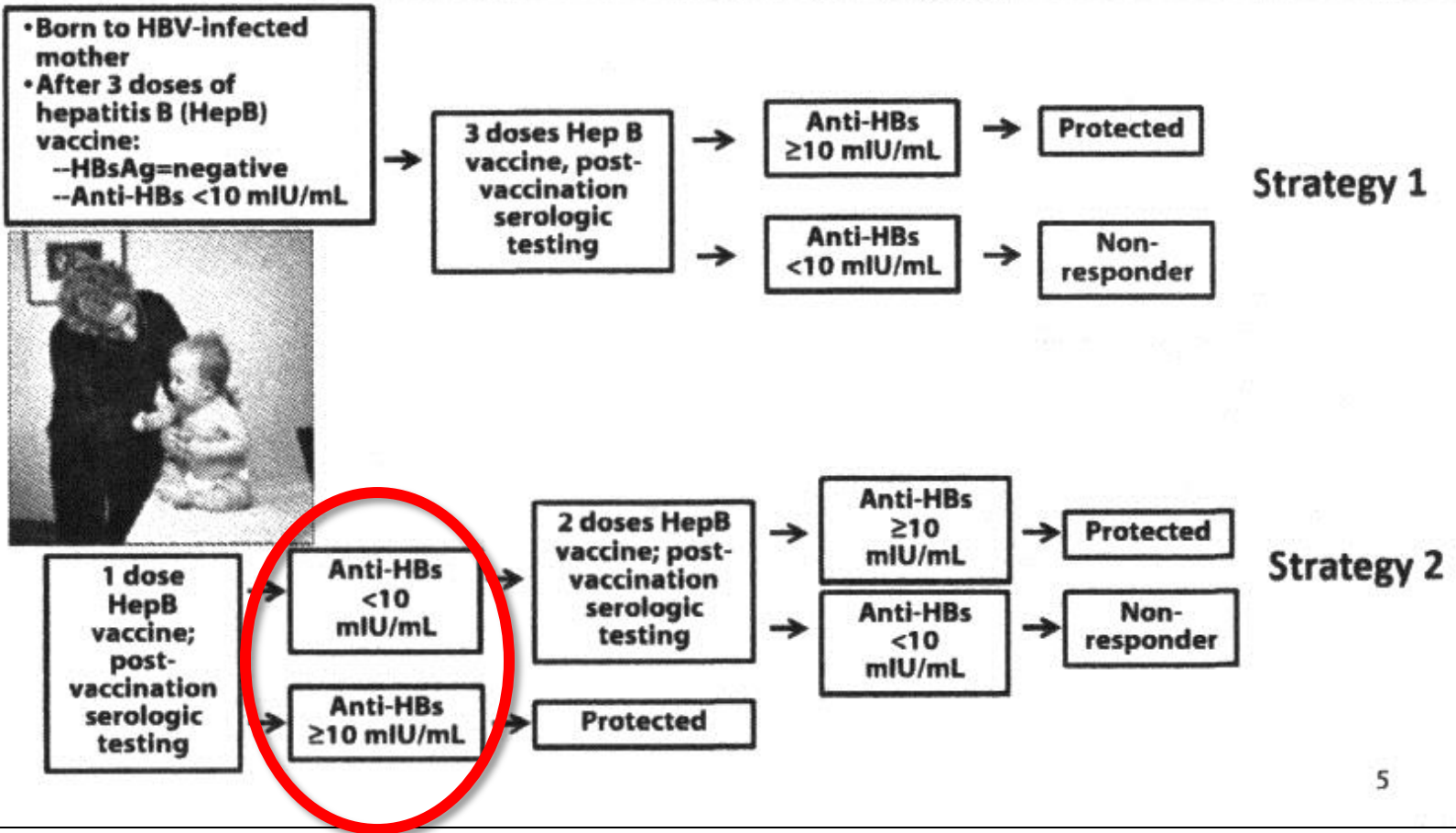
Hepatitis B Revaccination Strategies

Options for Revaccination of Infants Born to HBV-Infected Mothers



Hepatitis B Revaccination Strategies

Options for Revaccination of Infants Born to HBV-Infected Mothers



Hepatitis B Antibody Response to Single Dose Revaccination vs. 3 Dose Revaccination

- **Initial non-responder follow up study with 2 groups:**
 - **Group A with HBIG and 3 additional doses 96% seroconverted at 12 months, 100% after a 4th dose**
 - **Group B with 3 additional doses of vaccine, (no HBIG) 95.2% seroconversion at 12 months and 95.7% at 13 months after 4th dose**
- **94.8% AB+ of initial non-responders who complete a second 3 dose series**
- **14/15 (93.3%) had anti-HBs > 10mIU/ml after single dose revaccination (N=15)**

1Assateerawatt et al, Asian Pacific journal of allergy and immunology; 1991;

11(1)85-91

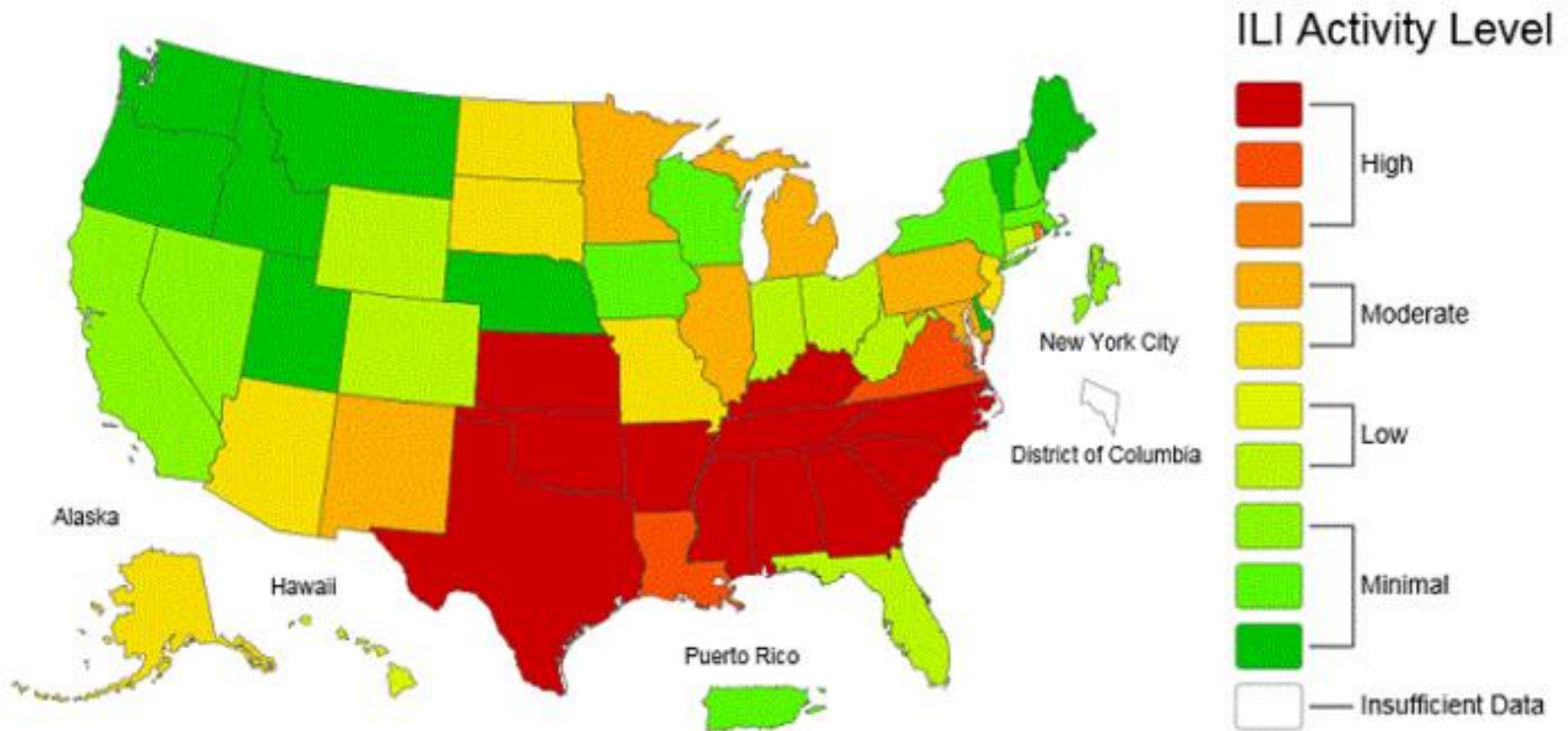
2Ko et al. Vaccine 2014; 32(18) 2127-33

3Perinatal Hep B Prevention Program 2012-2016 Georgia, Michigan, New York City

VOTE: Hepatitis B Revaccination for Infants Born to HBV+ Mothers

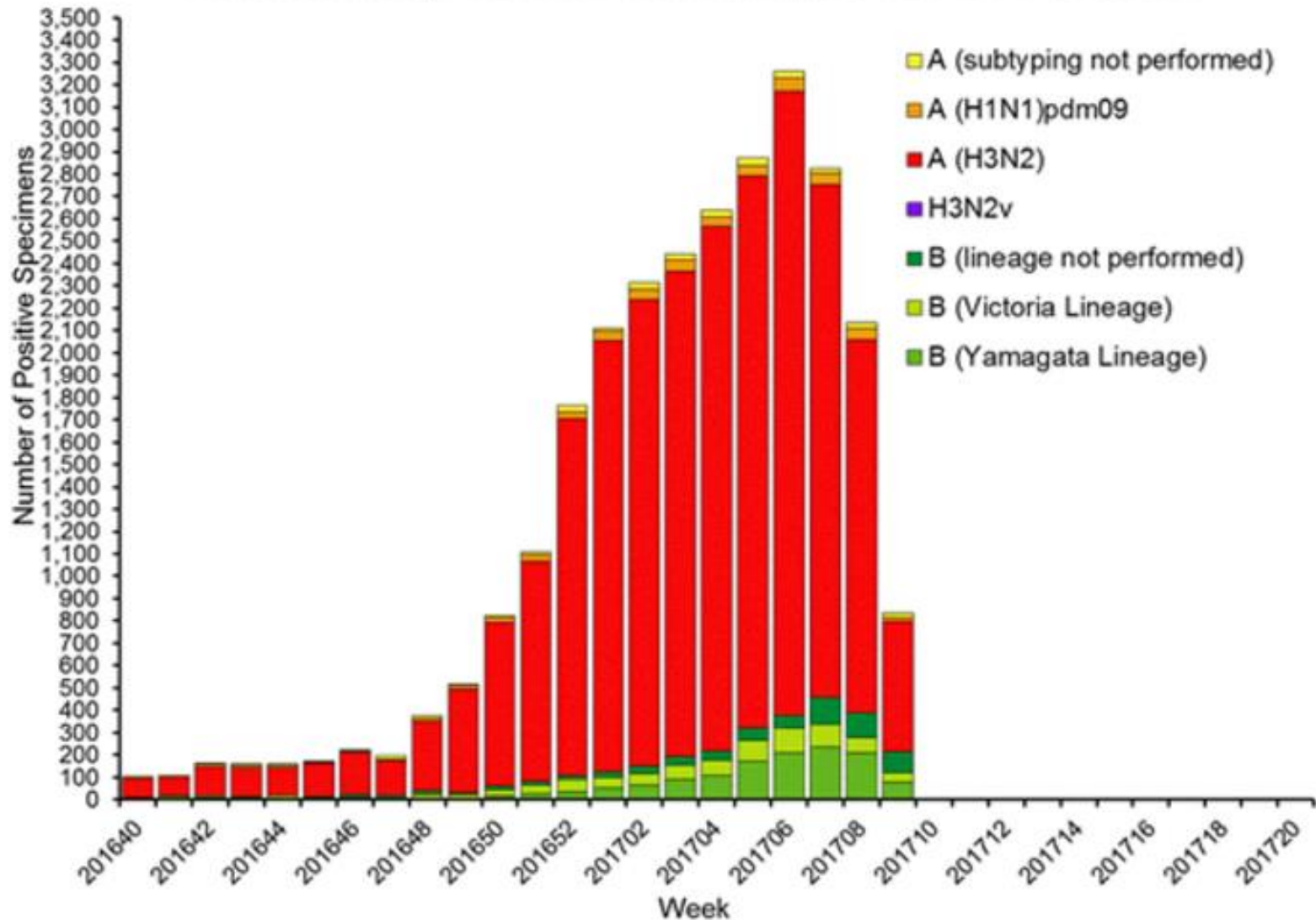
- **Initial management unchanged - testing after initial 3 dose series and if seropositive, no further vaccination**
- **If seronegative, may do one additional dose and retest after 1-2 months**
- **Language remains that allows for choosing to just repeat the 3 dose series without lab testing after the first dose followed by lab testing after the 6th dose**
 - **If anti-HBs is 10 mIU/mL or higher child is protected, no further vaccination or testing**
 - **If anti-HBs is less than 10 mIU/mL is a non-responder, no further vaccination or testing**

Influenza-Like Illness (ILI) Activity Level Indicator Determined by Data Reported to ILINet
2016-17 Influenza Season Week 9 ending Mar 04, 2017



www.cdc.gov/flu/weekly/index.htm, week ending March 4, 2017

Influenza Positive Tests Reported to CDC by U.S. Public Health Laboratories, National Summary, 2016-2017 Season



www.cdc.gov/flu/weekly/index.htm, week ending March 4, 2017

Influenza Current Season Surveillance

- Most circulating strains are A strains and predominantly H3N2; influenza B may just be starting
- Vaccine strains are a good match for the virus circulating in US (early vaccine effectiveness estimate 48%)
- Moderate season so far
- May have peaked in week 8
- 48 pediatric deaths to date
- Vaccine virus selection for 2017-2018 will be made in March by WHO

www.cdc.gov/flu/weekly/index.htm#ILIMap

Influenza Vaccine Updates

- **Afluria (Seqirus) evaluation of 2010 increase in adverse events of fever and febrile seizures in children <5 years in Southern Hemisphere CSL TIV**
- **ACIP recommends Afluria not be used in children younger than 9 years**
- **Root cause was TIV stimulated release of cytokines and chemokines more robustly than previously; manufacturing process may have not fully split the B virus adequately yielding a greater immune response**
- **Problem appears to be resolved, similar fever rates in TIV and QIV**

CDC panel recommends against using FluMist vaccine

POSTED 7:45 PM, JUNE 22, 2016, BY CNN WIRE

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TWITTER

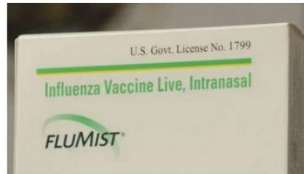
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PINTEREST

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Flu vaccines are about to get more painful. A Centers for Disease Control and Prevention advisory committee recommended on Wednesday that FluMist, the nasal spray influenza vaccine, should not be used during the upcoming flu season.



FluMist (Mark Ralston/AFP/Getty Images)

"To everyone's surprise and increasing consternation, this vaccine has performed quite poorly compared to the injectable vaccine," said Dr. William Schaffner, an infectious disease specialist.

An alternative to the standard flu shot, FluMist had been approved for people between the ages of 2 and 49 years old by the Food and Drug Administration.

The CDC committee, which includes 15 immunization experts, reviewed data from

AAP News

June 22, 2016

AAP backs new ACIP recommendation on influenza vaccine

AAP News staff

Health care providers should not use live attenuated influenza vaccine (LAIV) in the upcoming 2016-'17 season due to poor effectiveness, a Centers for Disease Control and Prevention (CDC) committee said Wednesday.

Academy leaders say they support the interim recommendation by the CDC's Advisory Committee on Immunization Practices (ACIP).

"We agree with ACIP's decision today to recommend health care providers and parents use only the inactivated vaccine for this influenza season," said AAP President Benard Dreyer, M.D., FAAP.

The AAP recommends children ages 6 months and older be immunized against influenza every year. Previously, the CDC and AAP had recommended either form of flu vaccine – the inactivated influenza vaccine (IIV) that is given by injection and is approved for all patients older than 6 months, or LAIV which is given by intranasal spray and is approved for healthy patients ages 2 through 49 years.

LAIV Influenza Vaccine Updates

- MedImmune presented review of 2015-2016 vaccine effectiveness data of LAIV against influenza hospitalization in 6 studies; CDC VE network showed no effectiveness compared to consolidated other sites in England, Finland, Canada, etc. at 54.5%
- Two potential hypotheses:
 - Reduced replication of H1N1 component in human cells
 - Vaccine virus interference by quadrivalent formulation
- Will be using a different H1N1 strain for 2017-2018 vaccine

LAIV Influenza Vaccine Updates

- **Committee had multiple questions before considering using LAIV:**
 - **More human studies**
 - **Better understanding of original US vaccine failure**
 - **Non-manufacturer studies**
- **LAIV not recommended in the coming season**

Herpes Zoster Vaccines

- **Zostavax (Merck); live, attenuated vaccine, 1 dose**
 - 2008 - ACIP recommended for immunocompetent persons 60 years and older
- **Efficacy: 51% vs zoster; 67% vs PHN**
 - Reduced in older recipients
- **Duration of protection vs zoster**
 - Year 4 - 45%
 - Year 9 - 7%
- **31% adults age 60 years or older in US have been vaccinated**

New Herpes Zoster Vaccine

- **Subunit vaccine (HZ/su), 2 doses**
 - Surface glycoprotein E + ASO1B adjuvant
- **Efficacy: 97% vs zoster in persons ≥ 50 years**
 - 91% vs zoster in persons ≥ 70 years
- **Duration of protection vs zoster**
 - Year 4- 85% in persons ≥ 70 years
- **More local reactions than with Zostavax**

N Engl J Med 2016;375:1019-32

Herpes Zoster Work Group Deliberations

- **Gaps:**
 - HZ/su protection beyond 4 years?
 - Efficacy in immunocompromised patients?
- **Considerations:**
 - Recommend HZ/su routine age 50 vs. 60 years?
 - Recommended for Previous Zostavax recipients?

Adult Immunization

- **Standards for Adult Immunization Practice (2014)**
 - **ACCESS** vaccination status at every encounter
 - **Strongly RECOMMEND** needed vaccines
 - **ADMINISTER** vaccines or **REFER** to a vaccine provider
 - **DOCUMENT** vaccines received in a state registry

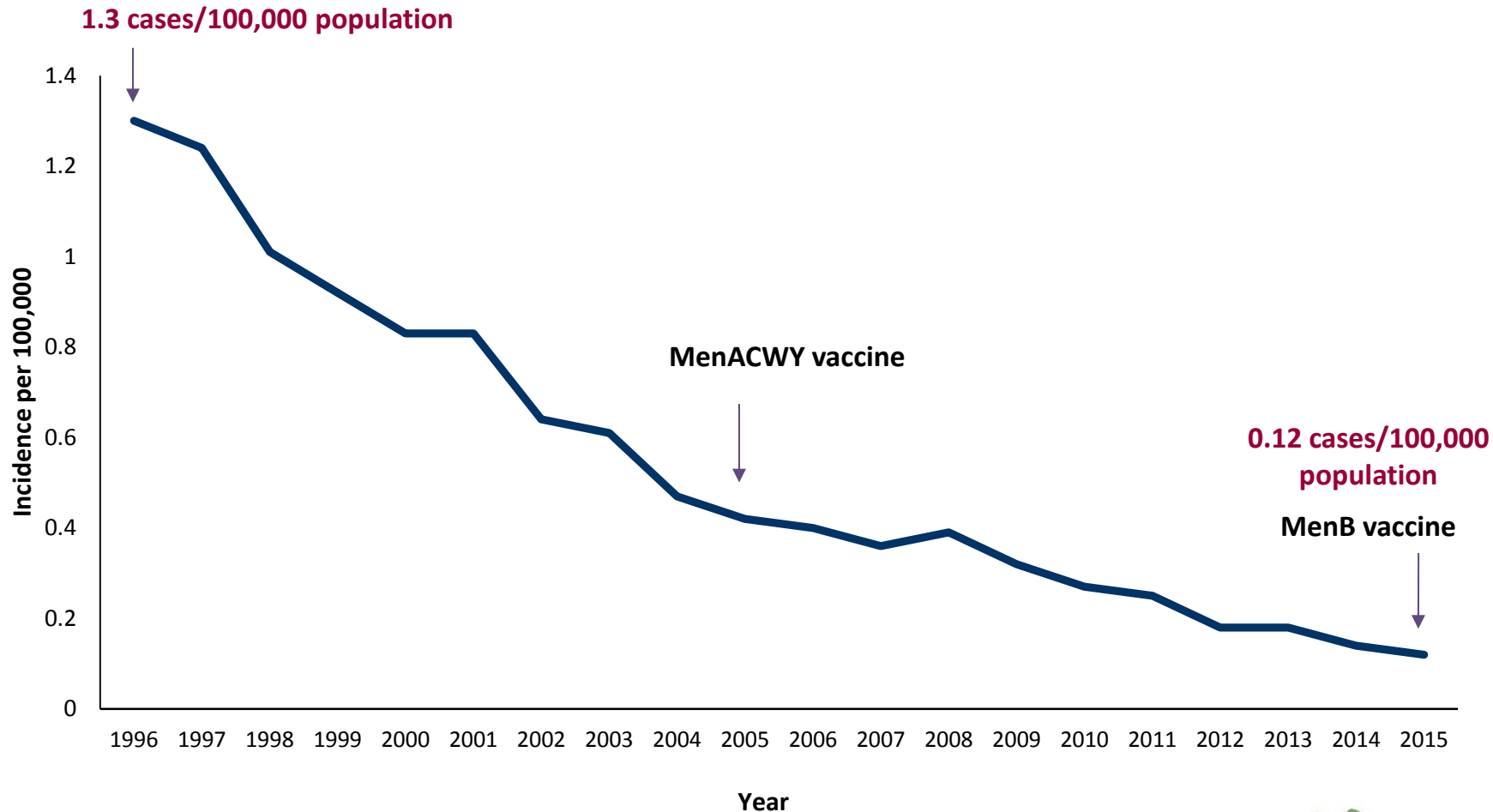
Adult Immunization

- **Online survey of adults and healthcare professionals (2016)**
 - **Adult patients reported low levels of care that reflected the Standards**
 - **Vaccination assessment 9%-53%**
 - **Providers reported high levels of Standards implementation**
 - **Vaccination assessment 67%-97%**

Meningococcal Vaccines

- **Sanofi Pasteur discontinuing production and supply of**
 - **Menomune (polysaccharide vaccine)**
 - **Last lots will expire June–September 2017**
- **A licensed meningococcal vaccine for persons age 56 years and older will not be available**
- **Persons age 56 years and older should receive MenACWY conjugate vaccine**

Meningococcal Disease Incidence – United States, 1996-2015



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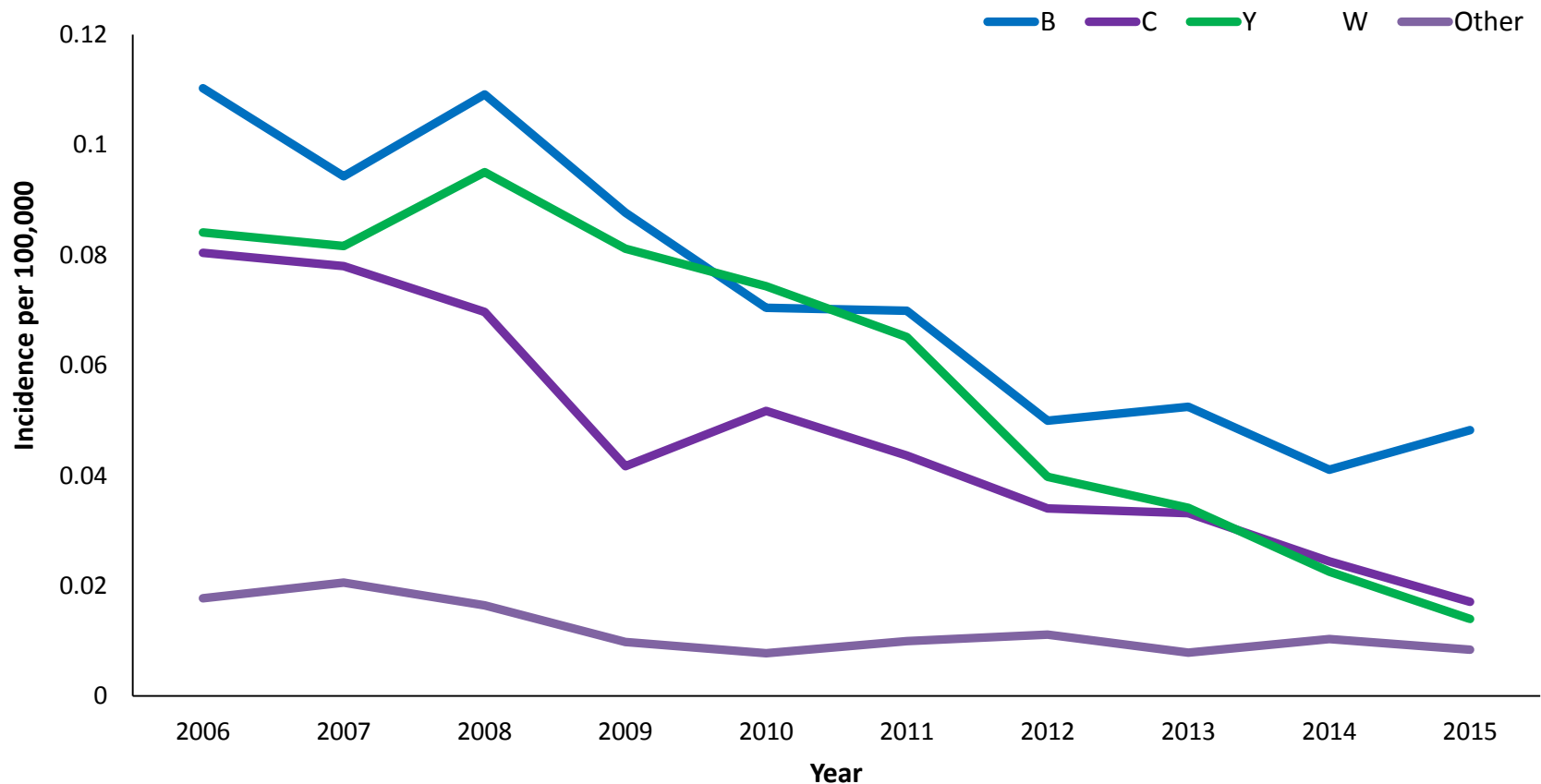
Hosted by the Missouri Department of Health and Senior Services, Bureau of Immunization Assessment and Assurance

•Abbreviations: MenACWY = quadrivalent conjugate meningococcal vaccine against serogroups A, C, W, Y; MenB vaccines = serogroup B meningococcal vaccines

•Source: 1996-2015 NNDSS Data

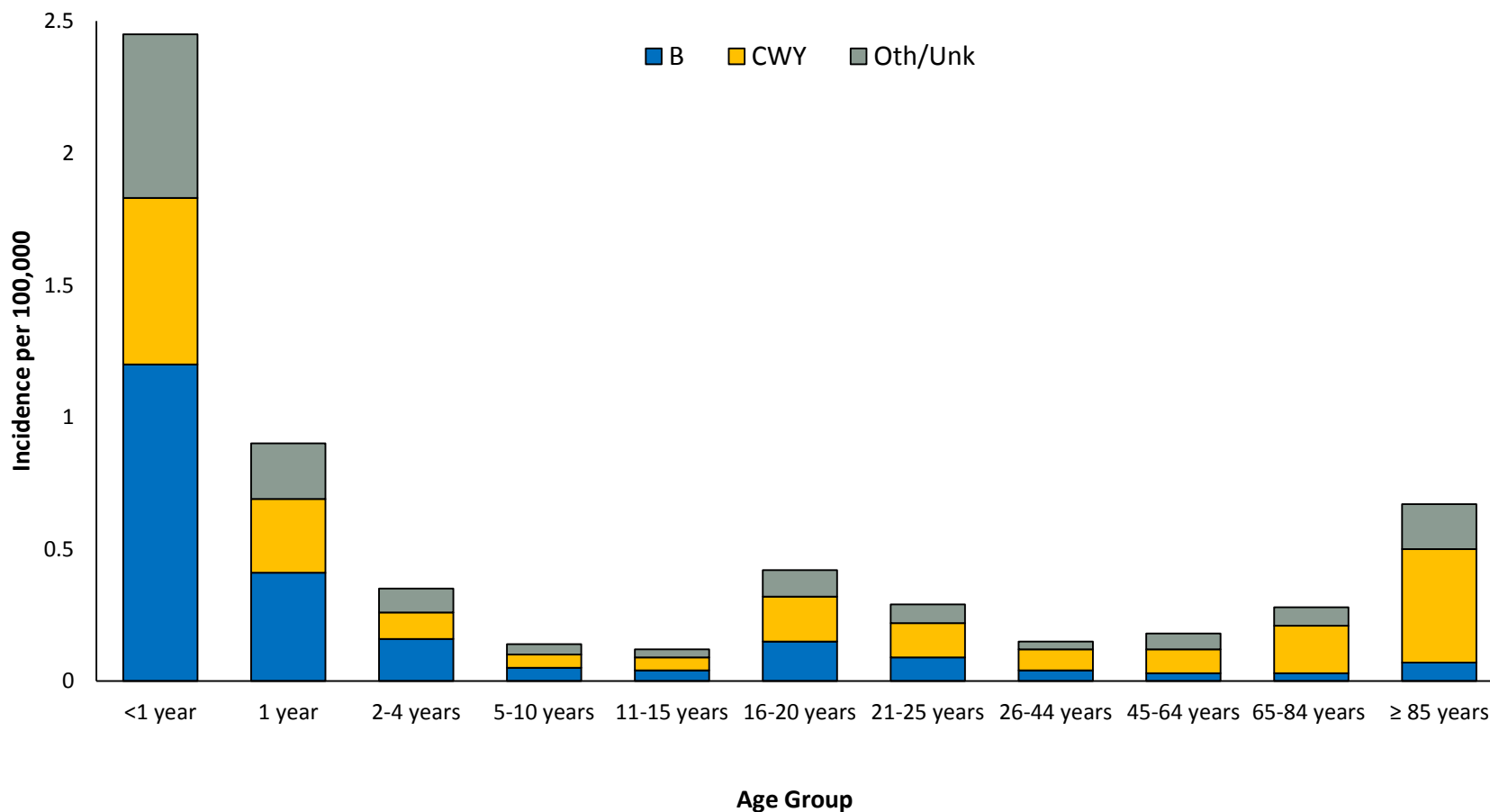
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Trends in Meningococcal Disease Incidence by Serogroup – United States, 2006-2015



National Notifiable Diseases Surveillance System (NNDSS) data with additional serogroup data from Active Bacterial Core surveillance (ABCs) and state health departments

Average Annual Incidence by Age-Group and Serogroup—United States, 2006-2015



National Notifiable Diseases Surveillance System (NNDSS) data with additional serogroup data from Active Bacterial Core surveillance (ABCs) and state health departments

Two MenB Vaccines For Persons Aged 10–25 Years in the United States

- **MenB-FHbp (Trumenba, Pfizer)**
 - Components: fHbp subfamily A/v2,3; subfamily B/v1
 - Licensed in the US on October 29, 2014
 - 3-dose series, administered at 0, 1–2, and 6 months
 - For persons at increased risk for serogroup B meningococcal disease
 - 2-dose series, administered at 0 and 6 months
 - For healthy adolescents who are not at increased risk for meningococcal disease
- **MenB-4C (Bexsero, GlaxoSmithKline)**
 - Components: fHbp subfamily B/v1; NhbA; NadA; Por A1.4
 - Licensed in the US on January 23, 2015
 - 2 dose series, administered at 0 and ≥ 1 month
 - Licensed in >35 countries for persons ≥ 2 months of age

Current ACIP Serogroup B Meningococcal (MenB) Vaccine Recommendations

- **February 2015**
 - Persons age 10 years and older who are at increased risk for meningococcal disease should receive MenB vaccine (Category A)¹. These include:
 - Persons with persistent complement component deficiencies
 - Persons with anatomic or functional asplenia
 - Microbiologists routinely exposed to isolates of *Neisseria meningitidis*
 - Persons identified as at increased risk because of a serogroup B meningococcal disease outbreak
- **June 2015**
 - Adolescents and young adults aged 16–23 years may receive MenB vaccine to provide short-term protection against most strains of serogroup B meningococcal disease (Category B)²
- **No guidance for booster doses**

1. MMWR; June 12, 2015; Vol. 64, No. 22, p 608-612.

2. MMWR; October 23, 2015, Vol. 64, No. 41, p 1171-1176.

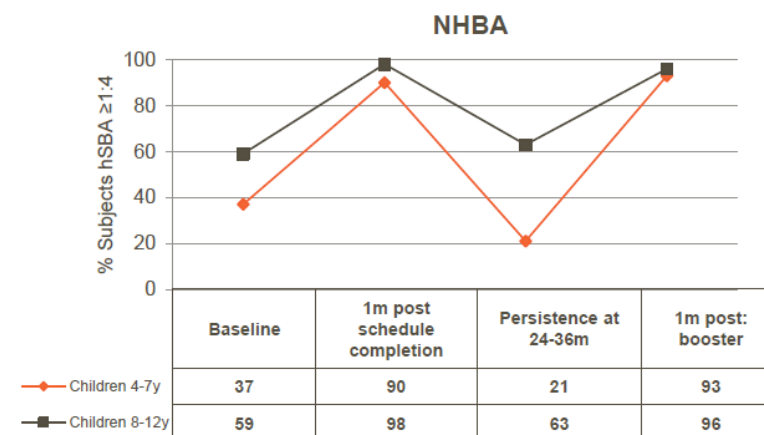
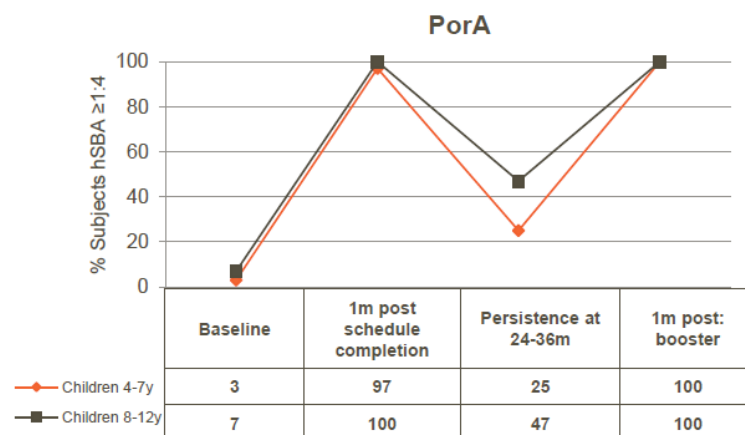
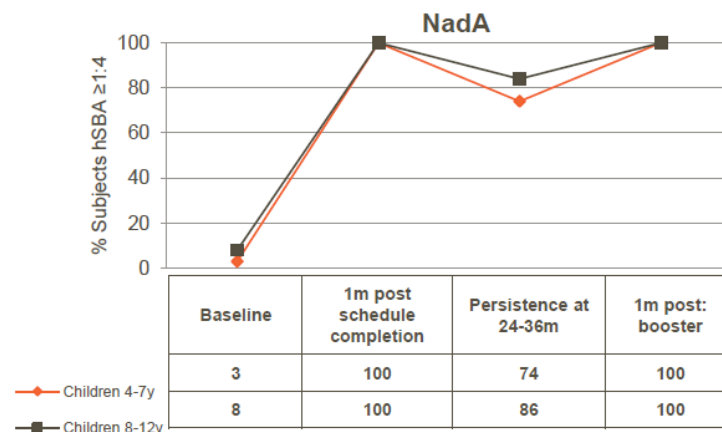
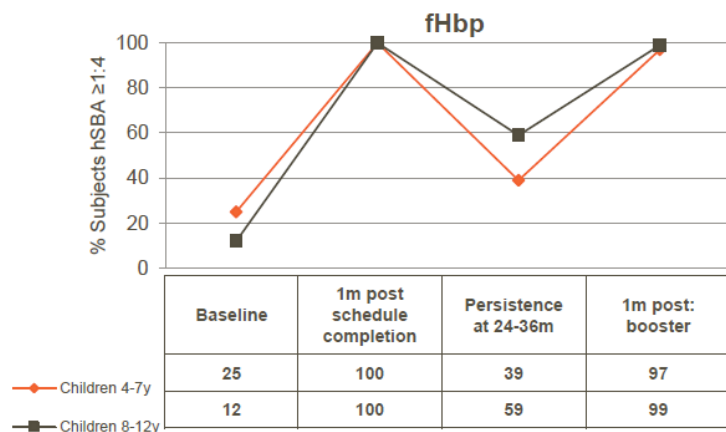
Statement of Problem

- **Certain persons at increased risk for meningococcal disease likely remain at increased risk throughout their lifetime**
 - **Persons with persistent complement component deficiencies or taking eculizumab**
 - **Persons with anatomic or functional asplenia**
 - **Microbiologists routinely exposed to isolates of *Neisseria meningitidis***
- **Data suggest waning of protection after vaccination with serogroup B meningococcal (MenB) vaccines**

Statement of Problem

- **Limited data on:**
 - **Duration of protection of MenB vaccines among persons at increased risk**
 - **Efficacy of MenB booster doses among persons at increased risk**
 - **Immunogenicity to primary series among immunocompromised subjects**
 - **Unlikely more data will be available**
- **Need to optimize protection for persons at increased risk for meningococcal disease**

MenB-4C (Bexsero®) - Antibody persistence (hSBA $\geq 1:4$) at 24–36 months post primary series and hSBA responses to a booster dose at 24–36 months post primary series in children aged 4–7 and 8–12 years



Confidential - Not for promotion or distribution

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Summary: MenB Vaccine Antibody Persistence and Booster Response Among Healthy Children and Adolescents

- **Decay of antibody levels against all strains for both MenB vaccines**
 - **Infants, children, adolescents**
 - **As early as 12 months**
 - **Different waning rates observed for antibodies to each antigen**
- **Increase in antibody levels among previously vaccinated subjects in response to a booster dose**

Policy Options

- **Booster doses of MenB vaccine should be administered every ? years throughout life to persons aged ≥ 10 years in each of the following groups:**
 - **Persons with persistent complement component deficiencies including persons taking eculizumab**
 - **Persons with anatomic or functional asplenia**
 - **Microbiologists routinely exposed to isolates of *Neisseria meningitidis* (as long as exposure continues)**
- **Booster doses of MenB vaccine should be administered to persons identified as at ongoing increased risk because of a serogroup B meningococcal disease outbreak based on a minimum interval since their last MenB dose (interval to be further discussed)**

Global Immunization Update

- **Polio**
 - Advancing toward eradication
 - Last endemic areas Afghanistan, Pakistan, Nigeria
 - Strategy: Surveillance, virus detection
 - Oral Polio Vaccine (OPV) change to Inactivated Polio Vaccine (IPV)
 - Research laboratory survey
- **Measles**
 - 79% reduction in cases, 2000-2015 (Target: 95%)
- **Rubella**
 - Only 46% of the world's children are vaccinated against rubella

Global Immunization Update

- **Dengue vaccine**
 - Recombinant tetravalent live attenuated vaccine (Dengvaxia[®], Sanofi Pasteur)
 - Safe, partial protection when given to children living in endemic areas with high background of previous dengue infection
- **Zika vaccines**
 - Several Zika vaccine candidates are entering Phase I clinical trials
- **Yellow Fever vaccine**
 - The shortage of Yellow Fever vaccine is being resolved
 - Product ordering restrictions will continue through mid-2017

Vaccination Errors

- **Vaccine Adverse Event Reporting System (VAERS) in 2000-2013 311,185 reports, 7% are error reports (21,843)**
- **Main errors are inappropriate schedule (27%), storage and dispensing (23%) and wrong vaccine (15%) - 2/3rds of errors**
- **Top 3 vaccines with errors often sound alike**
 - **Varivax/Zostavax**
 - **DTaP/Tdap**
 - **IIV age indication issues**
 - **Pneumo Conjugate/Pneumo Polysaccharide**
 - **Hep A/Hep B**

Hibbs et al. *Vaccine* 2015;33:3171–3178

Vaccination Errors

- **75% of vaccination errors reports to VAERS did not document adverse health events (AE)**
- **Of the 25% error reports that did have AE they were similar to non-error related reports; 92% are non-serious reports**
- **Case studies: rotavirus injected, insulin instead of influenza, injecting diluent**

Strategies for Reducing Vaccination Errors

- Education and training on the schedule
- Training on administration techniques
- Monitor vaccine storage temperatures
- Pay attention to expiration dates
- Engineer differentiation between sound alike names/acronyms
- Screening for contraindications standardized
- Engineered interventions
- Bar coding for box and product to match

Southeast Missouri State University reports 15 mumps cases, Vaccine clinics scheduled for next week

by NEWS DESK

🕒 March 5, 2017

📰 [US News](#)

💬 No Comments

1065 views

In light of recent reports of 15 confirmed mumps cases on the Southeast Missouri State University campus, The Missouri Department of Health and Senior Services has updated its recommendation and is encouraging all Southeast Missouri State University students to consider getting a third dose of the Measles, Mumps and Rubella (MMR) vaccine in response to continued confirmed and suspected cases of Mumps at the school.



Southeast News
@se_news

+ Follow

State health officials recommending [@SEMissouriState](#) students get 3rd MMR vaccine. Vaccine Clinics offered next week bit.ly/2mP3G8w

Because the majority of those cases are within the fraternity and sorority community, the Cape Girardeau Public Health Center, with assistance from the Campus Health Clinic, will host a vaccination clinic for all members of the Greek Community – including those living on- and off-campus – from 10 a.m.-7 p.m. Tuesday, March, 7 in the

Towers Complex, second floor. This vaccination clinic is specifically for members of Southeast's Greek community, who

Mumps Epidemiology

- Mumps vaccine has reduced disease by 99%
- Mumps outbreaks persist 2006, 2010, 2016 (nearly 6,000 cases)
- Most are in fully vaccinated college students
- If vaccine immunity is waning why are there no older vaccinated cases
- 2-dose schedule may be sufficient for general population
- 3 doses may be offered in outbreaks
- Benefit of 3rd dose in general population needs assessing

Mumps Disease and Vaccine

Questions for the Workgroup

- Why do we see mumps primarily in a tight age-range of teens and young adults? (19-23 years median in 16 outbreaks)
- When the outbreaks occur, they are largely on college campuses where there are close living situations, but we don't similarly see mumps outbreaks in military recruits. Why not?
- If we are seeing waning immunity of the vaccine how does that explain specific geographic outbreaks and no cases in older adults?
- Are certain populations at higher risk for mumps disease compared to others?

Mumps Disease and Vaccine Questions for the Workgroup

- Are there proper vaccine storage and handling concerns in certain areas?**
- Has there been a shift in mumps genotypes in the US compared to what is in the vaccine?**
- Should a 3rd dose of mumps containing vaccine be used in an outbreak setting only or is there evidence to support a 3rd dose as a more broad routine recommendation?**

- **Slides from ACIP meeting are usually available in 4-6 weeks after the meeting on the ACIP website**
- **Meeting minutes available within 90 days**
- **Next meeting June 21-22, 2017 in Atlanta**

Questions?